K123507

510(k) SUMMARY

APR 4 2013

KCI NPWT Gauze Dressing

Date prepared	March 4, 2013
510(k) owner	
• **Name**	KCI USA, Inc. (Kinetic Concepts, Inc.)
• **Address**	6203 Farinon Drive; San Antonio, Texas 78249
• **Phone number**	210 255-6345
• **Fax number**	210 255-6727
• **Name of contact person**	Anona Goebel
Name of the device	
• **Trade or proprietary name**	*KCI NPWT Gauze Dressing*
• **Common or usual name**	Negative pressure wound therapy system (gauze dressing component)
• **Classification name**	Negative pressure wound therapy powered suction pump (and components)
• **Legally marketed device(s) to which equivalence is claimed**	Smith and Nephew's RENASYS™ Gauze NPWT Wound Dressing Kit with Softport 510(k) Number: K110647
Device description	
• **Device design**	The *KCI NPWT Gauze Dressing* is a convenience kit that consists of the following currently marketed products: • One Kerlix AMD Roll, identical to predicate (antimicrobial gauze wound dressing) • One V.A.C. SensaT.R.A.C.™ Pad (connection to KCI NPWT source) • Two V.A.C. Drapes • One wound measuring ruler The currently marketed sterile products are kitted in a non-sterile package. The kit is provided in one size and is intended to be single use.
• **Indications for Use**	The *KCI NPWT Gauze Dressing* is intended to be used with the following KCI Therapy Units (ActiV.A.C.®, InfoV.A.C.®, V.A.C. Simplicity™, V.A.C.® Freedom, V.A.C. ATS® and V.A.C.Ulta™ Therapy Systems). The system is intended to create an environment that promotes wound healing by secondary or tertiary (delayed primary) intention by preparing the wound bed for closure, reducing edema, promoting granulation tissue formation and perfusion, and by removing exudate and infectious material. Wound types include chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic, pressure or venous insufficiency), flaps and grafts. The KCI NPWT Gauze Dressing is not intended for use with instillation

	therapy, intermittent therapy or over closed incisions.

• Summary of the technological characteristics of the device compared to the predicate device	**Feature**	**KCI NPWT Gauze Dressing**	**Predicate Renasys Gauze NPWT Dressing Kit**
	Dressing		
	• Material	Same as predicate	Antimicrobial gauze (Polyhexamethylene Biguanide 0.2%)
	• Configuration	Identical to the large size of the predicate	Multiple sizes available in roll and pad for small, medium and large wounds
	Drape	Currently marketed V.A.C. Drape (polyurethane film with acrylic adhesive)	Polyurethane film with adhesive
	Interface pad and tubing	Currently marketed V.A.C. SensaT.R.A.C.™ Pad	Softport assembly
	Wound measuring ruler	Same as predicate	Provided
	Accessories: Saline, skin prep, non-adherent layer	Not provided	Provided
	NPWT Therapy Units Compatibility	Compatible with the following KCI V.A.C. Negative Pressure Wound Therapy Units: ActiV.A.C. InfoV.A.C. V.A.C. ATS V.A.C. Freedom V.A.C. Simplicity V.A.C.Ulta	Compatible with S&N therapy units: RENASYS EZ RENASYS GO
Summary of non-clinical tests conducted for determination of substantial equivalence	The *KCI NPWT Gauze Dressing* was evaluated under a number of design verification and validation tests to assure performance requirements for delivery of negative pressure wound therapy were met. • The KCI NPWT Gauze Dressing when used with the V.A.C. Negative Pressure Wound Therapy Units delivers negative pressure within specification to the top of the wound site for a period of 72 hours. • The KCI NPWT Gauze Dressing when used with the V.A.C. Negative Pressure Wound Therapy Units removes exudate from the wound for a period of 72 hours. • The KCI NPWT Gauze Dressing when used with the V.A.C. Negative Pressure Wound Therapy Units do not contribute to false blockage alarms.		
Summary of clinical tests conducted for	None required for determining substantial equivalence		

determination of substantial equivalence	
Conclusions drawn	Testing demonstrates that the *KCI NPWT Gauze Dressing* and the RENASYS™ Gauze NPWT Wound Dressing Kits with Softport are substantially equivalent in terms of both indications for use and delivery of negative pressure wound therapy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

April 4, 2013

KCI USA, Inc.
% Ms. Anona Goebel
Senior Manager, Regulatory Affairs
6203 Farinon Drive
San Antonio, Texas 78249

Re: K123507
Trade/Device Name: KCI NPWT Gauze Dressing
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: Class II
Product Code: OMP, FRO
Dated: March 04, 2013
Received: March 07, 2013

Dear Ms. Goebel:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours, FOR

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K123507
Device Name: KCI NPWT Gauze Dressing

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Prescription Use ____X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Posted November 13, 2003)

Jiyoung Dang -S

(Division Sign-Off)
Division of Surgical Devices
510(k) Number: K123507